K032188

JUL 3 1 2003

12.0 Concluding 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Name of Manufacturer, Contact Person and Date Summary Prepared:**

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-940-7260
FAX: 949-940-7313
Contact Person: Jimmy Wong, Manager of Clinical and Technical Affairs
Date Prepared: July 11, 2003

2. **Device Name:**

Trade/Proprietary Name:	Nichols Advantage® Aldosterone
Common Name:	Aldosterone immunoassay
Classification Name:	Radioimmunoassay, Aldosterone

3. **Classification:** Class II
   Regulation Number: 862.1045
   Product Code: CJM, Clinical Chemistry

4. **Predicate Device:** Diagnostic Product Corporation Coat-A-Count Aldosterone

5. **Device Description:**
   The Nichols Advantage® Aldosterone assay contains sufficient reagents for 100 tests. The assay is a competitive binding assay for aldosterone in human serum or plasma.

6. **Intended Use:**
   The Nichols Advantage® Aldosterone assay is intended for use with the Nichols Advantage® Specialty System to quantitatively measure aldosterone in human serum and EDTA plasma. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte **imbalance**.

7. **Comparison to Predicate Device:**
   The Nichols Advantage® Aldosterone (Y) was compared to the DPC Coat-A-Count Aldosterone RIA (X) previously cleared by the FDA (K831178, 5/27/83). One hundred three (103) remnant serum samples in which the clinical diagnosis were unknown were assayed in duplicate by both methods following each manufacturers' directions. The range observed with method "X" was 2.7 to 125 ng/dL; range for method "Y" was 2.7 to 120 ng/dL. Passing Bablok regression analysis of these data yielded an equation of $Y = 1.04X + 0.1$ (95% confidence intervals for slope and intercept were 0.98 to 1.10, and -1.0 to +1.1 respectively). Deming regression analysis of these data yielded an equation of $Y = 1.09X - 0.6$ (95% confidence intervals for slope and intercept were 1.03 to 1.15, and -3.2 to +2.1 respectively). Pearson's correlation coefficient (r) of the paired data was 0.96.

8. **Similarities:**

- Specimen type is identical for both methods.
- Both assays use human aldosterone standards, and both report values using the same units: ng/dL.
- Both assays use a specific antibody to aldosterone, use competitive protein binding with labeled aldosterone to measure the hormone directly in serum or plasma samples.

9. Differences:

The following differences pertain to differences in immunoassay technology and do not affect the intended uses of each assay.

Feature	Nichols Aldosterone	DPC Aldosterone
Sample Size:	250 µL serum or EDTA plasma	200 µL serum or plasma
Binding Technology	Magnetic particles - avidin coated	Antibody coated tubes
Incubation steps and temperature:	3 steps, 10 minutes each @ 37°C	18 hours @ 15-28°C
Analytical sensitivity	1.2 ng/dL	1.1 ng/dL
Sample Bias	EDTA values are lower	EDTA values are higher

10. Comparison of Performance Characteristics

Feature	Nichols Aldosterone	DPC Aldosterone
Within-Run Precision (%CV)	2.9-14.0%	2.3-5.4%
Total Precision (%CV)	4.9-18.6%	3.8-15.7%
Recovery	88-110%	86-111%
Linearity	91-116%	100-119%

Conclusions: These data, which were provided to FDA, demonstrate safety and effectiveness of the Nichols Advantage® Aldosterone for its intended in vitro diagnostic use. Furthermore, based on performance characteristics, the Nichols Advantage® Aldosterone assay is substantially equivalent to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2003

Nichols Institute Diagnostics
c/o Alfredo J. Quattrone, Ph.D., DABT
California Department of Health
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234

Re: k032188
Trade/Device Name: Nichols Advantage Aldosterone
Regulation Number: 21 CFR 862.1045
Regulation Name: Aldosterone test system
Regulatory Class: Class II
Product Code: CJM; JIS; JJX
Dated: July 15, 2003
Received: July 17, 2003

Dear Dr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.0 Indications For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number: K032188

Device Name: Nichols Advantage Aldosterone

Indications for Use Statement: The Nichols Advantage® Aldosterone assay is intended for use with the Nichols Advantage® Specialty System to quantitatively measure aldosterone in human serum and EDTA plasma. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte **imbalance**.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032188

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X **Prescription Use** (Per 21 CFR 801.109) Or **Over –The-Counter Use** (Optional Format 1-2-96)